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TITLE: Online Early Resilience Intervention for Combat-Related PTSD in Military
Primary Healthcare Settings: A Randomized Trial of "DESTRESS-PC"

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14. ABSTRACT The broad objective of this research is to improve primary care mental health services for military personnel and veterans with post-traumatic stress disorder (PTSD) related to war-zone trauma. We hypothesize that a brief Internet-based online self-management tool for PTSD, DESTRESS-PC, based on empirically valid cognitive-behavioral therapy (CBT) strategies, will improve PTSD symptoms, related functional status, and attitudes regarding mental health treatment among veterans and military personnel with PTSD who are seeking primary health care after service in Operation Iraqi Freedom or Enduring Freedom (OIF/OEF). The last year has been spent preparing budgetary and contracting documents, getting IRB approval, and gearing up to begin recruitment. We now have full study approval from all necessary regulatory bodies and participant recruitment is underway.					
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Table of Contents

	<u>Page</u>
Introduction.....	1
Body.....	1
Key Research Accomplishments.....	1-2
Reportable Outcomes.....	2
Conclusion.....	2
References.....	2
Appendices.....	2

INTRODUCTION:

This randomized controlled trial will compare a cognitive-behavioral online self-management intervention (DESTRESS-PC) designed for primary care-delivered treatment of war-related PTSD to a control intervention, “optimized usual primary care PTSD treatment”. Optimized usual primary care will consist of PTSD diagnosis and referral back to the soldier’s primary care provider (PCP) followed by usual PCP guided treatment. Participants in both conditions will have scheduled check-ins with a study nurse to monitor their progress. The long term objective of the proposed research is to: 1) improve the readiness and resilience of military personnel who have symptoms from recent combat-related stressors; and 2) empower military primary care providers to assist personnel with PTSD symptoms following combat operations.

We expect that DESTRESS-PC will significantly decrease anxiety, depression, and physical symptoms, and improve overall health and occupational functioning relative to the optimized primary care condition. If this research project is successful, a provider-efficient model of care could be instituted in all DoD and VA primary care settings. By increasing the presence of available and effective PTSD treatment delivered in a primary care clinic with online psycho-education and therapeutic interventions, fewer military personnel will develop chronic PTSD. This is expected to improve the overall health of our patients and increase the military readiness of our service men and women.

BODY:

The main accomplishments of the last year as they pertain to the Statement of Work have been in the “Regulatory review process” and “Hire nurse managers and train nurse managers and clinic staff” categories; we have just begun to accomplish tasks from the third category “Conduct study”. The dual funding from DoD and NIMH led to some delays in the regulatory approval process. The process was set back in order for the study methodology to be expanded and improved to encompass both sets of funding and also for the respective budgets and SOWs to be revised to ensure that no funds were overlapping for the tasks to be performed on the study. The dual funding and multi-site nature of the study also caused a delay in the approval of two Cooperative Research and Development Agreements (CRADAs) for the study, which are now in place.

In terms of tasks laid out in the Statement of Work, we have prepared a study protocol and consent form, which was submitted, along with a set of appendices containing the complete study measures, to the four site IRBs for approval. Study approval was granted by the last of the four site IRBs in February of 2008. USAMRMC issued final IRB approval in June 2008, following requested changes to the Boston and Charleston protocols and consents, which were submitted at the two site IRBs and approved. Two DESTRESS Nurses have been hired for the Savannah VA clinic (part of the Charleston VA site) and for the Womack Army Medical Center (WAMC) site. The Savannah nurse has completed 15 hours of DESTRESS website, nurse manual, and clinical assessment training, and has been credentialed at the Charleston VA to perform the duties of the study. The WAMC nurse is scheduled to begin work during the first week of August, and will complete the same training later in August. The study Principal Investigator, COL Charles Engel, the Site Principal Investigator, Dr. Kathy Magruder, and the site coordinator, Derik Yeager administered a PTSD training and study orientation for the Savannah VA clinic, and are scheduled to conduct a similar training at the WAMC clinics (Robinson and Family Medicine) the first week of September. All the necessary materials (study assessment packets, randomization scheme, etc.) are in order to allow the nurses to enroll participants. The Savannah nurse has begun recruitment and has conducted consent and eligibility screening with one person, who was deemed ineligible. She has a second person scheduled for a screening appointment. We expect that the first study participant will be enrolled and randomized within the next one to two weeks.

KEY RESEARCH ACCOMPLISHMENTS:

- Budgets and Statements of Work reconciled for dual funding mechanisms.
- Protocol, consent form, and HIPAA prepared and submitted to regulatory agencies for approval.
- Nurse manual and DESTRESS website prepared and finalized for use.

- Subcontracts were created for the Charleston VA and Boston VA sites.
- IRB approval issued at 4 study sites (Charleston VA, Boston VA, WRAMC, and WAMC), as well as secondary IRBs (the U.S. Army Clinical Investigation Regulatory Office (CIRO), the Uniformed Services University of the Health Sciences (USUHS), and USAMRMC's Human Research Protection Office (HRPO)).
- Two CRDAs (between CIRO, Walter Reed Army Medical Center (WRAMC), and the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF) were prepared and ratified
- Office space, equipment, and supplies were procured for one of the two Charleston VA sites and the WAMC site.
- Study materials, including packets for determining eligibility, baseline, and follow-up, were assembled.
- Two DESTRESS Nurses were hired for the Savannah clinic at the Charleston VA site and the WAMC site.
- The nurse hired for the Savannah site completed 15 hours of training on the web-based intervention, the nurse manual, and use of the PTSD assessment tools.
- Members of the study team administered a PTSD training and study orientation at the Savannah VA clinic and are scheduled to conduct the training at the WAMC clinics next month.
- Recruitment began at the Savannah VA clinic in early July.
- One person has completed consent and eligibility screening; a second person is scheduled for a consent/eligibility appointment next week.

REPORTABLE OUTCOMES:

Since participant enrollment has not yet begun, there are no outcomes to report.

CONCLUSION:

Since participant enrollment has not yet begun, there are no results or conclusions to report.

REFERENCES:

Litz, BT, Williams, L, Wang, J, Bryant, R, Engel, CC (2004). A therapist-assisted internet self-help program for traumatic stress. *Professional Psychology: Research and Practice*, 35, 628-634.

Litz, B, Engel, CC, Bryant, R, Papa, A (2007). A randomized, controlled proof of concept trial of an internet-based therapist-assisted self-management treatment for PTSD. *American Journal of Psychiatry*, 164, 1-8.

Kuehn, BM (2008). VA, military seek office-based PTSD care. *JAMA*, 299, 1885-1886.

APPENDICES:

N/A

SUPPORTING DATA:

N/A